



POLICY ISSUE **(Notation Vote)**

January 15, 2019

SECY-19-0008

FOR: The Commissioners

FROM: Margaret M. Doane
Executive Director for Operations

SUBJECT: DENIAL OF PETITIONS FOR RULEMAKING REGARDING
LINEAR NO-THRESHOLD MODEL AND STANDARDS FOR
PROTECTION AGAINST RADIATION (PRM-20-28, PRM-20-29,
AND PRM-20-30)

PURPOSE:

To obtain Commission approval to deny three petitions for rulemaking (PRM-20-28, PRM-20-29, and PRM-20-30).

BACKGROUND:

The U.S. Nuclear Regulatory Commission (NRC) received petitions for rulemaking (PRMs) from Dr. Carol Marcus, Mr. Mark Miller, CHP, and Dr. Mohan Doss, et al. (collectively, the petitioners) in correspondence dated February 9, February 13, and February 24, 2015, respectively. The petitioners request that the NRC amend Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, "Standards for Protection Against Radiation," based on what they assert is new science and evidence that contradicts the linear no-threshold (LNT) dose-effect model that serves as the basis for the NRC's radiation protection regulations. On June 23, 2015, the NRC published in the *Federal Register* (FR) a notice docketing the PRMs and requesting public comment (80 FR 35870). The public comment period was initially set to close on September 8, 2015, but

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was extended to November 19, 2015, (80 FR 50804). The NRC received over 3,200 public comment letters.

DISCUSSION:

In 1991, the NRC issued the 10 CFR Part 20 final rule, that established the current regulatory framework for the NRC's radiation protection regulations (56 FR 23360; May 21, 1991). All NRC licensees are subject to the NRC's radiation protection requirements set forth in 10 CFR Part 20. These requirements are designed to protect both members of the public and occupational workers from harm that could be caused by a licensee's use of radioactive material. In accordance with 10 CFR 20.1101, "Radiation protection programs," each licensee "shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities."

The LNT model has been the underlying premise of much of the NRC's radiation protection regulations since the late 1950s. The LNT model provides that ionizing radiation is always considered harmful and that there is no threshold below which any amount of radiation exposure to the human body is not harmful. The LNT model further holds that biological damage caused by ionizing radiation (essentially, the cancer risk) is directly proportional to the amount of radiation exposure to the human body (response linearity). Thus, the higher the amount of radiation exposure, or dose, the higher the likelihood that the human receptor will suffer biological damage. The NRC's standards for protection against radiation, which are contained in 10 CFR Part 20, are underpinned by the LNT model. These radiation protection standards provide requirements for:

- Dose limits for radiation workers and members of the public;
- Monitoring and labeling radioactive materials;
- Posting signs in and around radiation areas; and
- Reporting the theft or loss of radioactive material.

The petitioners request that the NRC amend 10 CFR Part 20 to discontinue use of the LNT model as the primary scientific basis for the agency's radiation protection standards. The petitioners' main assertion is that the use of the LNT model is no longer valid based on various scientific studies. In particular, the petitioners advance the concept of radiation hormesis, which posits that low doses of ionizing radiation protect against the deleterious effects of high doses of radiation and result in beneficial effects to humans. Therefore, the petitioners request that the NRC amend its dose limits for radiation workers and members of the public as follows:

- Maintain worker doses at present levels, with allowance of up to 100 mSv (10 rem) effective dose per year if the doses are chronic;
- Remove the As Low As Is Reasonably Achievable (ALARA) principle entirely from the regulations, as it makes no sense to decrease radiation doses that are not only harmless, but may be hormetic;
- Raise the public dose limits to be the same as the worker doses, as these low doses may be hormetic; and

- End differential doses to pregnant women, embryos and fetuses, and children under 18 years of age.

As described in the enclosed *Federal Register* notice (FRN), the staff has concluded that there is lack of consensus in the scientific community regarding the level of risk associated with low doses of radiation and that there is substantial doubt within the scientific community regarding the validity of the hormesis concept.

The NRC's use of the LNT model as the basis for its radiation protection regulations is premised upon the findings and recommendations of national and international authoritative scientific bodies that have an expertise in the science of radiation protection. These bodies include, domestically, the National Academy of Sciences (NAS) and the National Council on Radiation Protection and Measurements (NCRP), both federally chartered, and, internationally, the International Commission on Radiological Protection (ICRP) and the International Atomic Energy Agency. All four of these bodies support the continued use of the LNT model. It has been the longstanding practice of the NRC to generally follow the recommendations of these authoritative scientific advisory bodies.

Reports issued by NAS and NCRP, which endorsed the LNT model, were considered in developing the 1991 revision to 10 CFR Part 20. Since that time, additional studies have supported the use of the LNT model. For example, in 2001, the NCRP published Report No. 136, "Evaluation of the Linear-Nonthreshold Dose-Response Model for Ionizing Radiation," which reported the work of the NCRP's Scientific Committee 1-6. Scientific Committee 1-6 was charged with reassessing "the weight of scientific evidence for and against the linear-nonthreshold dose-response model, without reference to policy implications."¹ After a comprehensive review of many studies, the NCRP concluded that "[a]lthough other dose-response relationships for the mutagenic and carcinogenic effects of low-level radiation cannot be excluded, no alternate dose-response relationship appears to be more plausible than the linear-nonthreshold model on the basis of present scientific knowledge."²

Although the petitioners argue against the validity of NCRP Report No. 136, other studies also support its conclusion. For example, in 2006, the NAS published its Biological Effects of Ionizing Radiation (BEIR) VII report, "Health Risks from Exposure to Low Levels of Ionizing Radiation," the seventh in a series of reports that concern the health effects from low doses of radiation, and by extension, the appropriateness of the LNT model.³ The reports were prepared by the Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation, which was established by NAS for the purpose of advising "the U.S. government on the relationship between exposure to ionizing radiation and human health."⁴ The BEIR VII report

¹ NCRP, "Evaluation of the Linear-Nonthreshold Dose-Response Model for Ionizing Radiation," Report No. 136 (2001), at 1 (NCRP Report No. 136).

² *Id.*, at 7. See also *id.*, at 48-49 (The NCRP also stated "[t]herefore, if radiation-induced cancer results directly from the induction of mutations involved in the oncogenic pathway, the data reported do not support the existence of a threshold."); and *id.*, at 77 (The NCRP also noted that "the majority of studies report linear dose-response relationships in the lower dose range with the coefficient being quite similar to the alpha coefficient of the in vitro linear-quadratic dose-response curves.").

³ NAS, "Health Risks from Exposure to Low Levels of Ionizing Radiation, BEIR VII – Phase 2" (2006) (NAS BEIR VII). The BEIR VII report may be viewed online at <https://www.nap.edu/catalog/11340/health-risks-from-exposure-to-low-levels-of-ionizing-radiation>. The NRC was one of several Federal agencies that provided funding to NAS for the BEIR VII study.

⁴ *Id.*, at vii.

focused on health effects from low doses of radiation (below 10 rem or 100 mSv) and updated the findings of the previous report on the health effects of low dose radiation, the 1990 BEIR V.

The BEIR VII committee analyzed epidemiologic data and biological data, including a study of the survivors of the Hiroshima and Nagasaki atomic bomb attacks and studies of cancer in children. The BEIR VII committee found “that the preponderance of information indicates that there will be some risk, even at low doses” and “that there is no compelling evidence to indicate a dose threshold below which the risk of tumor induction is zero.”⁵ The BEIR VII committee further found “[w]hen the complete body of research on this question is considered, a consensus view emerges. This view says that the health risks of ionizing radiation, although small at low doses, are a function of dose.”⁶ The BEIR VII committee concluded that “current scientific evidence is consistent with the hypothesis that there is a linear, no-threshold dose-response relationship between exposure to ionizing radiation and the development of cancer in humans.”⁷

In addition to NCRP and NAS recommendations, the NRC’s radiation protection regulations were premised, to a large extent, upon the recommendations of ICRP Publication 26, “Recommendations of the International Commission on Radiological Protection,” several of which, in turn, were premised on the LNT model.⁸ The ICRP is an independent, international organization with more than two hundred volunteer members from approximately thirty countries across six continents. These members represent the leading scientists and policy makers in the field of radiological protection. Since 1928, ICRP has developed, maintained, and elaborated on the International System of Radiological Protection used world-wide as the common basis for radiological protection standards, legislation, guidelines, programs, and practice. In its Publication No. 99, “Low-dose Extrapolation of Radiation-related Cancer Risk,” the ICRP stated that “we are uncertain about the likelihood of a dose threshold, and that, in addition, if there should be a dose threshold, we are uncertain about what dose level it would be.”⁹ The ICRP further stated that “the mechanistic and experimental data discussed in this monograph tend to give weight to a non-threshold model, as do the solid tumour data in the Japanese atomic bomb study.”¹⁰ The ICRP concluded that the “LNT theory remains the most prudent risk model for the practical purposes of radiological protection.”¹¹ The ICRP reaffirmed this conclusion in its Publication No. 103, “The 2007 Recommendations of the International Commission on Radiological Protection.”¹² In Publication No. 103, the ICRP acknowledged that the LNT model was not “universally accepted as a biological truth” and that the possibility of a low-dose threshold could not be ruled out, but “because we do not actually know what level of risk is associated with very-low-dose exposure, [the LNT model] is considered to be a prudent judgement for public policy aimed at avoiding unnecessary risk from exposure.”¹³

Several other international studies, such as the Ionising Radiation and Risk of Death from

⁵ *Id.*, at 10.

⁶ *Id.*

⁷ *Id.*, at 323.

⁸ 56 FR at 23360. In its Publication 26, the ICRP states “[f]or radiation protection purposes it is necessary to make certain simplifying assumptions. One such basic assumption underlying the Commission’s recommendations is that, regarding stochastic effects, there is, within the range of exposure conditions usually encountered in radiation work, a linear relationship without threshold between dose and the probability of an effect.” ICRP Pub. No. 26.

⁹ ICRP, “Low-dose Extrapolation of Radiation-related Cancer Risk,” Pub. No. 99 (2005), at 108.

¹⁰ *Id.*

¹¹ *Id.*, at 113.

¹² ICRP, “The 2007 Recommendations of the International Commission on Radiological Protection,” Pub. No. 103 (2007), at 36 and 38, 65-67.

¹³ *Id.*, at A178 and A180.

Leukemia and Lymphoma in Radiation-monitored Workers (INWORKS) study¹⁴, show there is at least some risk from low doses of radiation.

Furthermore, the staff identified recent reports that continue to support the use of the LNT model. In a May 2017, article published in the *International Journal of Radiation Biology*, the NCRP's president, Dr. John D. Boice, Jr., supports the continued use of the LNT model. Dr. Boice states that "[t]he LNT model, at least at the current time, has been useful in radiation protection, e.g. a safety culture exists that encompasses the principle of 'as low as reasonably achievable' (ALARA) considering financial and societal issues," and in this context, notes that "worker exposures have dropped dramatically over the years."¹⁵ Given that epidemiological studies cannot demonstrate the validity of the LNT model for low doses (below 100 mSv), Dr. Boice further states that the use of the LNT model, combined with the technical and professional judgment of a competent regulator, provides "a prudent basis for the practical purposes of radiological protection."¹⁶ In his conclusion, Dr. Boice emphasized that the LNT model is not an appropriate mechanism to assess radiological risk but is the most appropriate model currently available for a system of radiological protection when coupled with the appropriate regulatory and technical judgment.¹⁷

Most recently, the NCRP, in a study funded by the NRC, recommends the continued use of the LNT model. Specifically, the NCRP conducted a re-evaluation of the LNT model based on new epidemiologic studies completed since the NCRP made its last formal recommendation regarding the use of the LNT model in NCRP Report No. 136.¹⁸ In April 2018, the NCRP released Commentary 27, "Implications of Recent Epidemiologic Studies for the Linear-Nonthreshold Model and Radiation Protection," which provides a detailed assessment of currently available epidemiologic evidence and concludes that "the LNT model ... should continue to be utilized for radiation protection purposes."¹⁹ The Commentary explains that while the LNT model "is an assumption that likely cannot be scientifically validated by radiobiologic or epidemiologic evidence in the low-dose range, the preponderance of epidemiologic data is consistent with the LNT assumption, although there are a few notable exceptions."²⁰ The Commentary concludes that the "current judgment by national and international scientific committees is that no alternative dose-response relationship appears more pragmatic or prudent for radiation protection purposes than the LNT model on the basis of available data, recognizing that the risk <100 mGy (10 rad) is uncertain, but small."²¹

The staff's position was also informed by the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI), which advises the NRC on policy and technical issues that arise in the regulation of the medical uses of radioactive material in diagnosis and therapy. The ACMUI is a committee authorized under the Federal Advisory Committee Act, which regulates the formation and operation of advisory committees by Federal agencies. The ACMUI membership includes health care professionals from various disciplines, who comment on proposed changes to NRC

¹⁴ K. Leuraud et al., "INWORKS: An International Cohort Study, *Lancet Haematology*, Vol. 2" (July 2015).

¹⁵ J. Boice, Jr., "The linear nonthreshold (LNT) model as used in radiation protection: an NCRP update," *International Journal of Radiation Biology*, Vol. 93, No. 10 (2017), at 1080 (Boice).

¹⁶ *Id.*

¹⁷ *Id.*, at 1089.

¹⁸ NCRP Report No. 136, "Evaluation of the Linear-Nonthreshold Dose-Response Model for Ionizing Radiation" (2001).

¹⁹ NCRP, "Implications of Recent Epidemiologic Studies for the Linear-Nonthreshold Model and Radiation Protection," Commentary 27 (April 24, 2018), at 139.

²⁰ *Id.*, at 140.

²¹ *Id.*

regulations and guidance; evaluate certain non-routine uses of radioactive material; provide technical assistance in licensing, inspection, and enforcement cases; and bring key issues to the attention of the Commission for appropriate action. On October 28, 2015, ACMUI issued a report that included the ACMUI's recommendation that the NRC continue to use the LNT model.²² The ACMUI report stated that determining the "'correct' dose-response model for radiation carcinogenesis remains an unsettled scientific question."²³ Although the report acknowledged that there "is a large, and growing, body of scientific literature as well as mechanistic considerations" that question the accuracy of the LNT model, the ACMUI determined that "very large-scale epidemiological studies with long-term follow-up would be needed to actually quantify any such risks or benefits" and that "such studies may be logistically and financially prohibitive."²⁴ According to the ACMUI report, "a mathematical extrapolation model remains the only practical approach to estimating the presumed excess cancer risk from low-dose radiation" and, therefore, the "dose-response data" derived from epidemiological studies of population cohorts exposed to high doses of radiation, such as those of the atomic bomb survivors, are "largely consistent" with the LNT model.²⁵ In making its recommendation, the ACMUI stated that it "recommends that, for the time being and subject to reconsideration as additional scientific evidence becomes available, the NRC continue to base the formulation of radiation protection standards on the LNT model."²⁶

Similarly, the public comments received by the NRC in the response to the FRN predominately supported the staff's current position on the LNT model. The NRC received over 3,200 comment submissions, with 635 of those comment submissions being unique, including comments from certified health physicists, nuclear medical professionals, other scientific professionals, scientific associations, Federal agencies, and concerned citizens. In determining the appropriate disposition of the petitions, the NRC carefully reviewed the comment submissions. To simplify the analysis, the NRC grouped all comment submissions into two main groups: those that opposed the petitions and those that supported them. As described in the draft FRN (Enclosure 1), the NRC received 100 unique comment submissions that agreed with the petitioners and 535 unique comment submissions that opposed the petitioners' recommendation to discontinue use of the LNT model as a basis for the NRC's radiation protection regulations. Notably, amongst the comment submissions opposed to the petitioners' recommendations, three were from Federal agencies: the U.S. Environmental Protection Agency, the National Cancer Institute/National Institutes of Health/Department of Health and Human Services, and the National Institute for Occupational Safety and Health/Centers for Disease Control and Prevention/Department of Health and Human Services. All three Federal agencies recommend that the NRC continue to use the LNT model.

Lastly, the petitioners assert that the cost of complying with LNT-based regulations is "enormous" and "incalculable." The NRC's 1991 revision to 10 CFR Part 20 established the current regulatory framework for the NRC's radiation protection regulations. In issuing that final rule, the Commission concluded that the rule "provides for a substantial increase in the overall protection of the public health and safety and that the direct and indirect costs of its implementation are justified in terms of the quantitative and qualitative benefits associated with the rule." Although the NRC acknowledges the costs involved in complying with its regulations,

²² ACMUI, "Final Report on the Hormesis/Linear No-Threshold Petitions" (October 28, 2015), at 1. Agencywide Documents Access and Management System Accession No. ML15310A418.

²³ *Id.*

²⁴ *Id.*, at 1-2.

²⁵ *Id.*, at 2.

²⁶ *Id.*, at 1.

the staff continues to conclude that the regulatory provisions that rely on LNT, such as the ALARA standard, remain both beneficial, in terms of the health and safety benefits they provide to members of the public and occupational workers, and cost-justified. The petitioners have not provided any new information that would cause the staff to revisit its findings with respect to cost that it made in 1991. Moreover, in the 1991 final rule, the Commission further noted that if it had determined that the rule was not cost-justified, the Commission would have still issued the rule "because the changes made to [10 CFR Part] 20 also amount to a redefinition of the level of adequate protection." The NRC is mandated under the AEA to impose requirements that it determines to be necessary for adequate protection of public health and safety regardless of cost.

The NRC staff finds that there is scientific uncertainty and no compelling evidence as to whether the hormesis concept is valid for application to radiation protection requirements. As described in this paper and the enclosed draft FRN, none of the national and international authoritative scientific advisory bodies support the hormesis concept as a regulatory model for radiation protection, nor do these bodies recommend the establishment of a dose threshold below which ionizing radiation would not be considered harmful. Therefore, the staff has determined that it is prudent to continue to rely upon the LNT model as a basis for the NRC's radiation protection regulations and to not make any changes to the NRC's current dose limits for radiation workers and members of the public.

RECOMMENDATION:

The staff recommends that the Commission deny PRM-20-28, PRM-20-29, and PRM-20-30 in their entirety. Given the current state of scientific knowledge, the staff has determined that the LNT model remains an effective model for its radiation protection regulatory framework. Thus, the staff recommends no change to the current dose limits for radiation workers and members of the public. The draft FRN (Enclosure 1) provides a detailed response to the assertions made in the three PRMs.

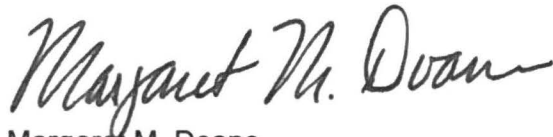
The staff requests the Commission's approval to publish the FRN denying PRM-20-28, PRM-20-29, and PRM-20-30. Should the Commission agree with the staff's recommendation to deny the petitions, the enclosed letters for signature by the Secretary of the Commission (Enclosures 2 through 4) would inform the petitioners of the Commission's decision. The staff would also inform the appropriate Congressional committees of the Commission's decision.

RESOURCES:

This paper does not address any new commitments or resource implications.

COORDINATION:

The Office of the General Counsel has no legal objection to the denial of these petitions.

A handwritten signature in black ink, reading "Margaret M. Doane". The signature is fluid and cursive, with the first name "Margaret" being more prominent than the last name "Doane".

Margaret M. Doane
Executive Director for Operations

Enclosures:

1. Draft *Federal Register* notice
2. Draft letter to Dr. Carol Marcus
3. Draft letter to Mr. Mark Miller, CHP
4. Draft letter to Dr. Mohan Doss

SUBJECT: DENIAL OF PETITIONS FOR RULEMAKING REGARDING LINEAR NO-THRESHOLD MODEL AND STANDARDS FOR PROTECTION AGAINST RADIATION (PRM-20-28, PRM-20-29, AND PRM-20-30), DATED JANUARY 15, 2019

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Commissioners' completed vote sheets/comments should be provided directly to the Office of the Secretary by COB Monday, February 4, 2019.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT Monday, January 28, 2019, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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